User Manual

CardEX[™] 300

3-Channel Electrocardiograph



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- The electrical installation of the relevant room complies with safety standards;
- The instrument is used in accordance with the instructions for use.

Note: This device is not intended for home use.

MARNING: This device is not intended for treatment.

Using This Label Guide

⚠WARNING⚠

A WARNING label advises against certain actions or situations that could result in personal injury or death.

©CAUTION

A CAUTION label advises against actions or situations that could damage equipment, produce inaccurate data, or invalidate a procedure.

Note: A NOTE provides useful information about a function or procedure.

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1 Safety Guidance

1.1 Safety Information

The design of CARDEXTM 300 3-channel electrocardiograph complies with international standard IEC/EN 60601-1 Medical Electrical Equipment: General Requirements for Safety and IEC/EN 60601-2-25 Particular Requirements for the Safety of Electrocardiographs etc. The classification of this equipment is Class I, type CF, which means a higher degree of protection against electric shock and the patient connection is fully isolated and defibrillation protected.

This equipment is not explosion-proof. Do not use it in the presence of flammable anesthetics.

This equipment is designed for continuous operation and is not drip or splash-proof.

Classification:

1) Anti-electric-shock type: Class I with internal power supply

2) Anti-electric-shock degree: CF

3) Degree of protection against harmful Sealed equipment without liquid proof

ingress of water:

4) Disinfection/sterilization method: Refer to the user manual for details

5) Degree of safety of application in the presence of flammable gas: Equipment not suitable for use in the presence of flammable gas

6) Working Mode: Continuous operation

7) EMC: Group I, Class A

1.2 Warnings and Cautions

In order to use the electrocardiograph safely and effectively, avoiding possible dangers caused by improper operations, please read through the user manual and be sure to be familiar with all functions of the equipment and proper operation procedures before use.

Please pay attention to the following warning and caution information.

1.2.1 Safety Warnings

MARNING:

- 1. The electrocardiograph is provided for the use of qualified veterinarian or personnel professionally trained. They should be familiar with the contents of this user manual before operation.
- 2. Only qualified service engineers can install this equipment. And only service engineers authorized by Midmark Corporation can open the shell.
- 3. Only qualified personnel can shift the mains shift switch (100V-115V~ / 220V-240V~) according to local mains supply.
- 4. The results given by the equipment should be examined with respect to the overall clinical condition of the animal. It cannot substitute for regular checking.

⚠WARNING⚠:

- 5. **EXPLOSION HAZARD**-Do not use the electrocardiograph in the presence of flammable anesthetic mixture with oxygen or other flammable agents.
- 6. **SHOCK HAZARD**-The power receptacle must be a hospital grade grounded outlet. Never try to adapt the three-prong plug to fit a two-slot outlet.
- 7. If the integrity of external protective conductor in installation or arrangement is in doubt, the equipment should be operated from the built-in rechargeable battery.
- 8. Do not use this equipment in the presence of high static electricity or high voltage equipment which may generate sparks.
- 9. This equipment is not designed for direct cardiac application.

⚠WARNING⚠:

- 10. Only patient cable and other accessories supplied by Midmark Corporation can be used, or else the performance and electric shock protection cannot be guaranteed.
- 11. Be sure that all electrodes have been connected to the animal correctly before operation.
- 12. Be sure that the conductive parts of electrodes and associated connectors, including neutral electrode, should not contact the ground or any other conducting objects.
- 13. Electrodes with defibrillator protection should be used while defibrillating.
- 14. There is no danger for animals with pacemaker. However, if a pacemaker is used, the results given by the equipment may be invalid, or lose the clinical significance.

- 15. Do not touch the animal, bed, table and the equipment while using defibrillator or pacemaker simultaneously.
- 16. In order to avoid burning, please keep the electrode far away from the radio knife while using electrosurgical equipment simultaneously.

AWARNING:

- 17. Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC/EN standards (e.g. IEC/EN 60950 for data processing equipment and IEC/EN 60601-1 for medical equipment). Furthermore all configurations shall comply with the valid version of the standard IEC/EN 60601-1-1. Therefore anybody, who connects additional equipment to the signal input connector or output connector to configure a medical system, must make sure that it complies with the requirements of the valid version of the system standard IEC/EN 60601-1-1. If in doubt, consult our technical service department or your local distributor.
- 18. The summation of leakage current should never exceed leakage current limits while several other units are used at the same time.
- 19. The potential equalization conductor can be connected to that of other equipment when necessary, to make sure that all these equipment are connected with the potential equalization bus bar of the electrical installation.

1.2.2 Battery Care Warnings

⚠WARNING⚠:

- 20. Improper operation may cause the battery to be hot, ignite or explode, and it may lead to the declination of battery's capacity. It is necessary to read the user manual carefully and pay attention to warning messages.
- 21. Only the battery of same model and specification provided by manufacturer should be used.
- 22. Danger of explosion -- Do not reverse the anode and cathode when connecting the battery.
- 23. Do not heat or splash the battery or throw it into fire or water.
- 24. When leakage or foul smell found, stop using the battery immediately. If your skin or cloth comes into contact with the leakage liquid, cleanse it with clean water at once. If the leakage liquid splashes into your eyes, do not wipe them. Irrigate them with clean water first and go to see a doctor immediately.
- 25. When the battery's useful life is over, contact the manufacturer or local distributor for disposal or dispose the battery according to local regulations.

1.2.3 General Cautions

CAUTION:

- 1. Federal (US) law restricts this device to sale by or on the order of a veterinarian.
- 2. Avoid liquid splash and excessive temperature. The temperature must be kept between 5° C and 40° D while working, and between -20° C and 55° C while transporting and storage.
- 3. Do not use the equipment in dusty environment with bad ventilation or in the presence of corrosives.
- 4. Be sure that there is no intense electromagnetic interference source around the equipment, such as radio transmitter or mobile phone etc. Attention: large medical electrical equipment such as electrosurgical equipment, radiological equipment and magnetic resonance imaging equipment etc. are likely to bring electromagnetic interference.

PCAUTION:

- 5. Before use, the equipment, patient cable and electrodes, etc., should be checked. Replacement should be made if there is any evident defectiveness or aging symptom which may impair the safety or performance.
- 6. The following safety checks should be performed at least every 24 months by a qualified person who has adequate training, knowledge, and practical experience to perform these tests.
 - a) Inspect the equipment and accessories for mechanical and functional damage.
 - b) Inspect the safety relevant labels for legibility.
 - c) Inspect the fuse to verify compliance with rated current and breaking characteristics.
 - d) Verify the device functions properly as described in the instructions for use.
 - e) Test the protection ground resistance according to IEC/EN60601-1: Limit 0.1 ohm.
 - f) Test the ground leakage current according to IEC/EN60601-1: Limit: NC 500 μA, SFC 1000μA.
 - g) Test the patient leakage current according to IEC/EN60601-1: Limit: NC a.c. $10\mu A$, d.c. $10\mu A$; SFC a.c. $50\mu A$, d.c. $50\mu A$.
 - h) Test the patient leakage current under single fault condition with mains voltage on the applied part according to IEC/EN60601-1: Limit: 50µA (CF).

- The data should be recorded in an equipment log. If the device is not functioning properly or fails any of the above tests, the device has to be repaired.
- 7. Ruptured fuse must only be replaced with the same type and rating as the original.
- 8. When the effective life time of the equipment and accessories is over, collect and classify them, and dispose them according to local regulations.

1.2.4 Cleaning & Disinfection Cautions

CAUTION:

- 9. Turn off the power before cleaning and disinfection. If mains supply used, the power cord should be unplugged from the outlet also. And prevent the detergent from seeping into the equipment.
- 10. Do not immerse the unit or patient cable into liquid under any circumstances.
- 11. Do not clean the unit and accessories with abrasive fabric and avoid scratching the electrodes.
- 12. Any remaining detergent should be removed from the unit and patient cable after cleaning.
- 13. Do not use chloric disinfectant such as chloride and sodium hypochlorite etc.

2 Introduction

CARDEXTM 300 is 3-channel electrocardiographs with 7 leads gathered simultaneously, visual display of operation menu, ECG parameters as well as electrocardiogram.

3-channel ECG can be viewed on the LCD (liquid crystal display) screen of CARDEX™ 300 simultaneously. And it can be recorded by the high-quality thermal recorder.

Auto, manual, rhythm, USB print and off mode can be chosen conveniently.

Either mains supply or built-in rechargeable Lithium battery can be used as power.

With a high resolution thermal printer, 32-bit processor and large capacity hard drive, CARDEXTM 300 has advanced performance and high reliability. The compact size makes it suitable for clinic and hospital use.

Components: Main unit and accessories (power cord, grounding wire, patient cable, electrodes and thermal record paper)

⚠WARNING⚠: This equipment is not designed for direct cardiac application.

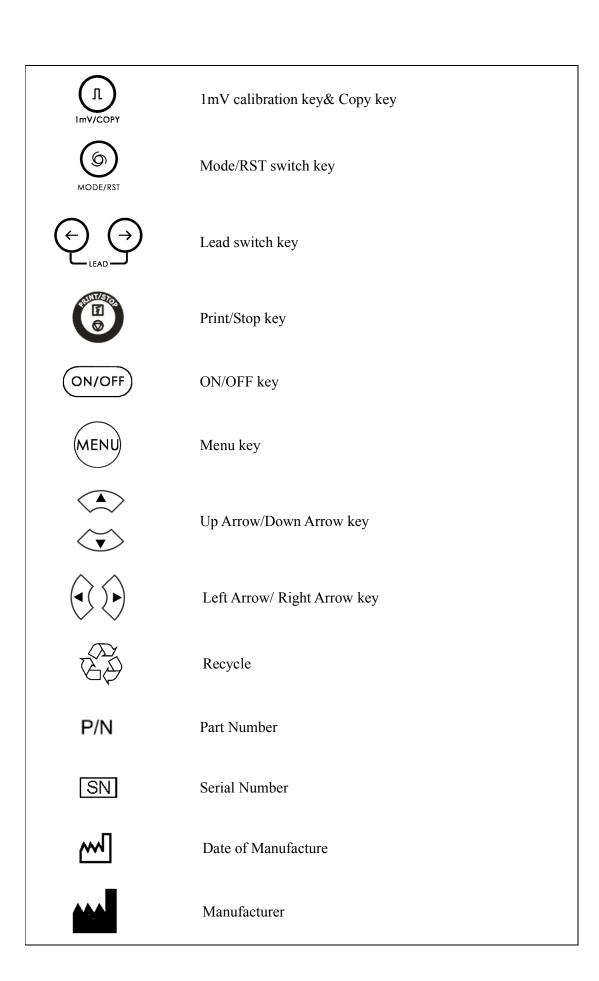
⚠ WARNING ∴: The results provided by the equipment should be examined with respect to the overall clinical condition of the animal. It cannot substitute for regular checking.

2.1 Function Features

- ♦ Low weight and compact size
- ♦ Touch key for easy operation
- ♦ High resolution thermal recorder, recording frequency response ≤150Hz
- ♦ 7-lead sampled and amplified simultaneously, 3-channel built-in recorder
- Auto mode, manual mode, rhythm mode, USB print mode and off mode optional
- ♦ Auto measurement function
- ♦ Built-in rechargeable Li battery with high capacity
- Alert for lead off, lack of paper and low battery capacity, etc.
- Automatic adjustment of baseline for optimal recording
- ♦ Standard input/output interface, RS232 communication interface and net port for linking to special network and setting up ECG database

2.2 List of Symbols

\rightarrow	External output
⊕	External input
4 \\	Equipment or part of CF type with defibrillator proof
\triangle	Caution
<u>(i</u>	Consult Instructions for Use
\Rightarrow	Potential equalization
\sim	Mains supply
I	On (mains supply)
0	Off (mains supply)
	Battery indicator
→ □	Battery recharging indicator
SENS	Sensitivity switch key
RECALL	Recall key



EC REP	Authorized Representative in the European Community
Rx only (U.S.)	Federal (US) law restricts this device to sale by or on the order of a veterinarian.
	It indicates that the device should be sent to the special agencies according to local regulations for separate collection after its useful life.

3 General Information

3.1 Top Panel



Figure 3-1 Main Unit

Product Information:

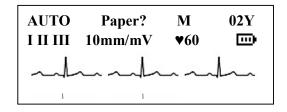
CardEX™ (Trade mark)

CardEXTM 300 Veterinary ECG (Trade name)

(Classification Symbol, equipment of CF type with defibrillator proof)

3.1.1 LCD Screen

The LCD Screen specification: 192×64 dot single color LCD Screen.



Normally, the contents displayed on the LCD screen include: (description from left to right)

First Row:

- Record mode (AUTO, MANUAL, RHYTHM, USBPRT or OFF)
- ♦ Alert information (Paper?, Printing, Sampling, Bat Weak etc.)
- ♦ Sex (M/F) and Age

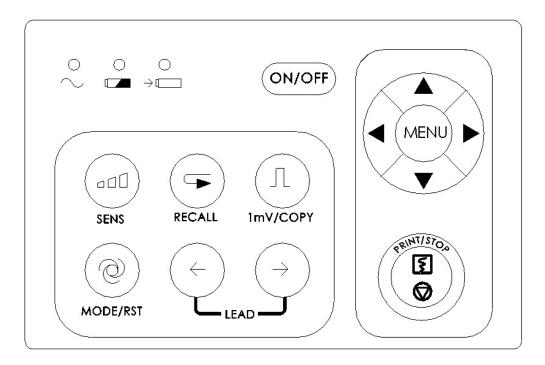
Second Row:

- ♦ Current lead (I, Π, Ш, aVR, aVL, aVF, V)
- ♦ Sensitivity (×2.5mm/mV, ×5mm/mV, ×10mm/mV, ×20mm/mV, AGC)
- ♦ Heart rate ♥ (Actual heart rate)
- Battery capacity (Only when the built-in battery is used)

Third Row:

♦ ECG wave

3.1.2 Control Panel and Keys



1) Indicator Lamp

- \sim Mains supply indicator light: when mains supply is used, the light will be lit.
- Battery indicator light: when the built-in rechargeable Lithium battery is used, the light will be lit.
- → Battery recharging indicator light: when the battery is recharged, this light will be lit.

2) SENS (Sensitivity Switch Key)



The sensitivity switching order: ×10 mm/mV→×20 mm/mV → AGC→×2.5 mm/mV→ ×5 mm/mV. And AGC means auto gain control.

3) Recall Key



Press this key to review the patient files saved in the recall window.

4) 1mV/COPY Key



Under MANUAL mode, this key can be pressed to record a 1mV calibration pulse at any time while recording.

Under AUTO mode, once a complete ECG was recorded, this key can be pressed to recall the electrocardiogram that recorded last time.

5) MODE/RST (Mode Switch Key)



MODE/RST

This key can be pressed to select recording mode between AUTO, MANUAL, RHYTHM, USBPRT and OFF. The switching order of lead groups is listed in Table 3-1.

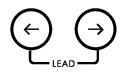
Recording under Manual mode, this key can be pressed to reset the waveform quickly.

⚠ WARNING ♠: When using the device with defibrillator, after the defibrillator discharge, the MODE/RST key should be pressed to reset the waveform quickly.

Table 3-1 Lead Group Switching order of Different Mode

Mode		Switching Order (from left to right)			
ALITO	Standard	I / II / III	aVR / aVL / aVF	V	
AUTO	Cabrera	aVL/ I /-aVR	II /aVF/ III	V	
MAN	IUAL	the lead switch order of	oress Lead Switch Key to can be that of AUTO (So termined by settings of ENU	tandard) or AUTO	

6) LEAD (Lead Switch Key)



Under MANUAL mode, press the key to switch the lead group.

In Recall window or Menu interface, this key can be pressed to turn the pages.

7) PRINT/STOP Key



Used to begin recording and stop recording.

8) ON/OFF Key



When the unit has been powered on, press this key to turn on it. Press again to turn off it.

9) MENU Key



Press this key to enter menu settings.

10) Up Arrow/Down Arrow





Pressing the Up Arrow or Down Arrow can select Sex or Age item on the main interface. (hereinafter called **Up/Down**)

During MENU setting, the two keys can also be pressed to select the item of which the setting is to be changed.

11) Left Arrow/Right Arrow





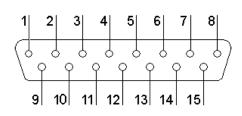
Press these keys to change the content of the selected item. During MENU setting, these keys can also be pressed to change the content of the selected item. (hereinafter called **Left/Right**)

3.2 Patient Cable Socket and Signal Interface

There are sockets including the patient cable socket, RS232 socket, external input/output socket and USB interface at the right side of the main unit as following Figure shows.



1) Patient Cable Socket



H: Applied part of type CF with defibrillator proof



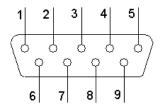
Definition of corresponding pins:

	Signal	Pin	Signal	Pin	Signal
1	NC	6	SH	11	F/LL (input)
2	NC	7	NC	12	NC
3	NC	8	NC	13	C /V(input)
4	NC	9	R /RA(input)	14	NC
5	NC	10	L/LA(input)	15	N or RF /RL(input)

Note: The left side of "/" is European standard; and the right side is American standard.

2) RS232 Socket

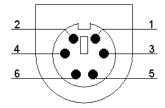
⚠WARNING : RS232 interface is 1500V AC isolated intensity and the maximum voltage applied should not exceed +15V DC.



Definition of corresponding pins:

Pin	Signal	Pin	Signal	Pin	Signal
1	NC	4	NC	7	NC
2	RxD (input)	5	GND	8	NC
3	TxD (output)	6	NC	9	NC

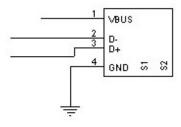
3) External Input/Output Socket



Definition of corresponding pins:

Pin	Signal	Pin	Signal
1	GND	4	GND
2	GND	5	ECG Signal (input)
3	GND	6	ECG Signal (output)

4) USB Interface



Definition of corresponding pins:

Pin	Signal	Pin	Signal
1	VBUS	3	D+
2	D-	4	GND

⚠WARNING ∴: Only the USB equipment recommended by Midmark Corporation can be connected to the USB interface.

⚠WARNING⚠:

- ◆ Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC/EN standards (e.g. IEC/EN 60950 for data processing equipment and IEC/EN 60601-1 for medical equipment). Furthermore all configurations shall comply with the valid version of the standard IEC/EN 60601-1-1. Therefore anyone who connects additional equipment to the signal input or output connector to configure a medical system, must make sure that it complies with the requirements of the valid version of the system standard IEC/EN 60601-1-1. If in doubt, consult our technical service department or your local distributor.
- ♦ The summation of leakage current should never exceed leakage current limits while several other units are used at the same time.

3.3 Mains Connection and Switch



1) Potential Equalization Terminal



Potential equalization conductor provides a connection between the unit and the potential equalization bus bar of the electrical installation.

2) Mains Supply Socket

∼ AC SOURCE: alternating current supply socket

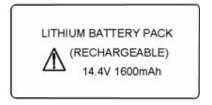
3) Power Switch

: Switch on : Switch off

3.4 Bottom Panel



1) Battery Compartment



The battery label indicates the rated voltage and rated capacity of rechargeable Lithium battery pack. Rated voltage: 14.4V, Rated capacity: 1600mAh.



⚠WARNING⚠:

Improper operation may cause the battery to be hot, ignite or explode, and it may lead to the decrease of battery's capacity. Therefore, it is necessary to read the user manual carefully and pay attention to warning messages.

MARNING:

When leakage or foul smell found, stop using the battery immediately. If the leakage liquid contact your skin or clothing, cleanse it with clean water at once. If the leakage liquid gets into your eyes, do not wipe them. Irrigate them with clean water first and go to see a doctor immediately.

MARNING:

Only the battery of same model and specification provided by manufacturer must be used.

2) Mains Supply Shift Switch



Mains supply with rated input voltage 230V (220V-240V~) or 115V (100V-115V~) can be chosen by the shift switch according to local mains supply specification.

WARNING : Only qualified personnel can shift the mains shift switch according to local mains supply.

3) Fuse

There are two fuses installed on the bottom of the main unit. The specification is showed on the fuse label: AC220V-240V: T200mA; AC100V-115V: T400mA; Φ 5×20.

FUSE AC220V-240V: T200mA AC100V-115V: T400mA Ø 5x20

WARNING: Ruptured fuse must only be replaced with the same type and rating as the original.

4 Operation Preparations

CAUTION: Before use, the equipment, patient cable and electrodes should be checked. Replace it if there is any evident defectiveness or aging which may impair the safety or performance. And be sure that the equipment is in proper working condition.

4.1 Power and Grounding

⚠ WARNING ⚠: If the integrity of external protective conductor in installation or arrangement is in doubt, the equipment should be operated from the built-in rechargeable battery.

The electrocardiograph can be powered either by mains supply or the built-in rechargeable lithium battery pack.

1) Mains supply

The mains connection socket is on the left of the unit. If mains supply used, connect the power cord to the socket first, and then connect the plug of the cord to the hospital grade outlet.

Rated input voltage: $100V-115V \sim /220V-240V \sim$

Rated frequency: 50Hz/60Hz

Rated input power: 35VA

Make sure the mains supply meets the above requirements before power on. And then press the mains power switch to power on the unit. Then the mains supply indicator light (\sim) will be lit.

If the built-in rechargeable battery is weak when mains supply used, it will be recharged automatically at the same time. And both the mains supply indicator light (\sim) and the battery recharging indicator light $(\rightarrow \Box)$ will be lit.

2) Built-in rechargeable battery

While using the built-in rechargeable lithium battery pack, turn on the unit by pressing **ON/OFF** key on control panel directly and the battery indicator light () will be lit.

The battery symbol will be displayed on the LCD screen. Because of the consumption during storage and transport, the capacity of battery may not be full. If the symbol and the alert information "BAT WEAK" are displayed, which means the battery capacity is weak, please recharge the battery first.

Please refer to the maintenance section for how to recharge the battery. During recharging the battery, CARDEXTM 300 can be powered by mains supply at the same time.

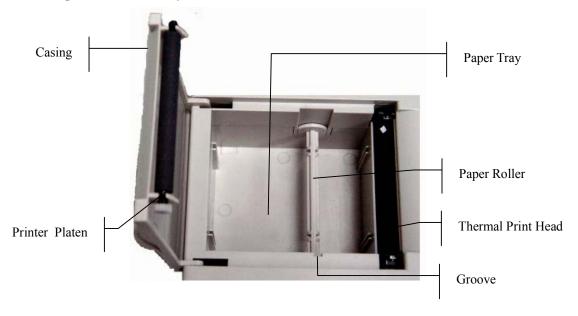
⚠WARNING⚠: Potential equalization conductor of the unit should be connected to the potential equalization bus bar of the electrical installation when necessary.

4.2 Loading/Replacing Record Paper

Two kinds of paper can be used as ECG record paper. One is rolled thermal paper with 80mm width, and the other is folded thermal paper with 80mm width.

Note: When using folded thermal paper, the Paper Roller is unnecessary, and it can be taken out.

When there is no recording paper loaded or it reaches the end of recording paper, warning message "Paper?" will be given on the screen. Under this circumstance, recording paper should be loaded or replaced immediately.



Loading/Replacing Process for rolled thermal paper:

- 1) Place fingers under the flange of the recorder casing, pull upwards directly to release the casing;
- 2) Take out the paper roller, and remove remain paper from the left of roller if necessary;
- 3) Take off the wrapper of thermal paper roll, and then put through the roller from the left with the paper's grid side facing downward;
- 4) Place the paper and roller gently in the recorder with the roller pin on the roller's left side facing to the groove;
- 5) Pull about 2cm of paper out, and put down the recorder casing;
- 6) Secure the casing by pressing it firmly.

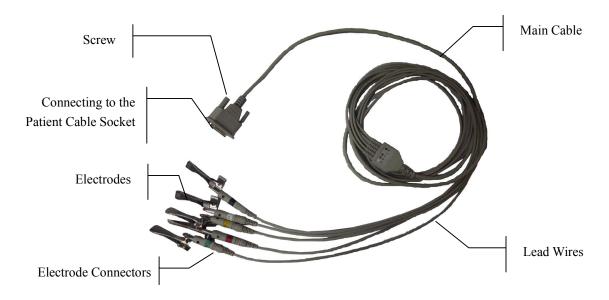
Loading/Replacing Process for Folded thermal paper:

- 1) Place fingers under the flange of the recorder casing, pull upwards directly to release the casing;
- 2) Remove residual paper in the Paper Tray if necessary;
- 3) Take off the wrapper of folded thermal paper, and then put it in the Paper Tray with the paper's grid side facing the thermal print head while putting the free end of paper upright;
- 4) Pull about 2cm of paper out, and close the recorder casing;
- 5) Secure the casing by pressing it firmly.

4.3 Patient Cable Connection

⚠WARNING⚠: The performance and electric shock protection can be guaranteed only if original Midmark Corporation patient cable and electrodes are used.

Patient cable includes two parts, main cable and lead wires with associated electrode connectors. The electrode connectors can be distinguished from the color and identifier on them.



Connect Main Cable: Plug the connector of main cable into the patient cable socket on the right side of the unit, and secure the screw.

4.4 Electrodes Connections

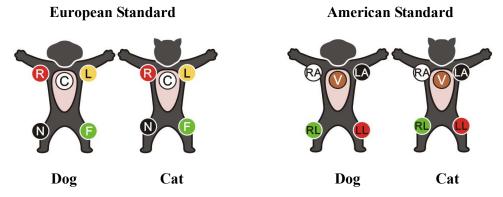


The identifier and color code of electrode connectors used complies with IEC/EN requirements. In order to avoid incorrect connections, the electrode identifier and color code is specified in Table 4-1.

Table 4-1 Electrodes, Identifier and Color Code

	European		Amo	erican
Electrodes	Identifier	Color code	Identifier	Color code
Right fore limb	R	Red	RA	White
Left fore limb	L	Yellow	LA	Black
Right rear limb	N or RF	Black	RL	Green
Left rear limb	F	Green	LL	Red
Chest	С	White	V	Brown

As the following figure shows, the electrode areas on body surface are:



The contacting resistance between the animal and the electrode will affect the quality of ECG greatly. In order to get a high-quality ECG, the skin/electrode resistance must be minimized while connecting electrodes.

Electrodes connection:

- 1) Ensure the electrodes to be clean;
- 2) Align lead wires of patient cable to avoid twisting;
- 3) Clean electrode area with alcohol;
- 4) Daub the electrode area with gel evenly;
- 5) Place a small amount of gel on the metal part of electrode clamp;
- 6) Clamp the electrode to the electrode area. Attach all electrodes in the same way.

⚠WARNING⚠: Be sure that all electrodes have been connected to the animal correctly before operation.

⚠WARNING⚠: Be sure that the conductive parts of electrodes and associated connectors, including neutral electrode, should not contact with the ground or any other conducting objects.

4.5 Inspection before Power On

In order to avoid safety hazards and get good ECG recordings, the following inspection procedure is recommended before power on and operation.

1) Environment:

- Check and make sure that there is no electromagnetic interference source around the equipment, especially large medical electrical equipment such as electrosurgical equipment, radiological equipment and magnetic resonance imaging equipment etc. Switch off these devices when necessary.
- Keep the examination room warm to avoid muscle action voltages in ECG signal caused by cold.

2) Power Supply:

- If mains power used, please check whether the power cord has been connected to the unit well. A grounded three-phase outlet should be used.
- Recharge the battery first when the battery capacity is weak before use.

3) Patient Cable:

• Check whether the patient cable has been connected to the unit firmly, and keep it far away from the power cord.

4) Electrodes:

- Be sure that all electrodes have been connected to the animal correctly.
- Ensure that the electrodes haven't contacted each other.

5) Recorder Paper:

• Ensure that there is enough recorder paper loaded correctly.

6) Animal:

- The animal should not be making contact with conducting object such as metal part of table, etc.
- Ensure the animal is warm and relaxed, and breathing calmly.

⚠WARNING⚠: The electrocardiograph is provided for the use of qualified veterinarian or personnel professionally trained. And they should be familiar with the contents of this user manual before operation.

5 Operation Instructions

5.1 Switching On

- ◆ While using mains supply, press the power switch on the left side of the unit first, and the mains supply indicator light (∼) is lit. Then press **ON/OFF** key on the control panel to turn on the unit. Equipment information such as device name and version No. will be displayed on LCD screen after self-test. Then CARDEX™ 300 is ready for examination and recording.
- ◆ While using built-in rechargeable lithium battery, press **ON/OFF** key on the control panel directly to turn on the unit, and then the battery indicator (□ will light. After self-test, CARDEXTM 300 is ready for examination and recording.

5.2 AUTO Mode

Under AUTO mode, the lead groups are switched in order automatically while recording. When ECG signal of one lead group has been recorded, it will be switched to another lead group automatically and begin recording the ECG signal of that lead group. There is a blank on the recording paper before recording the next ECG signal. Moreover, a 1mV calibration mark will be recorded at the beginning of recording. The lead group switching order is listed on Table 3-1.

Operation Method:

- 1) Press **MODE/RST** key to choose AUTO mode, which will be displayed in the top left corner on LCD screen:
- 2) Press **MENU** key to enter the Menu window to set the recording settings. Press it again to return after setup;
- 3) Press **PRINT/STOP** key to begin recording. It will stop automatically after recording a full ECG.

Pressing PRINT/STOP again during the course of recording can stop recording. However, when beginning recording later, ECG will be recorded from the first lead group again. And ID number will change automatically according to the current time. If the ID number needs to be unchanged, the user should adjust it before recording.

Note: Whether under auto or manual mode, recording mode cannot be changed during the course of recording. Stop recording before choosing recording mode.

Note: Under OFF mode, the sampled ECG waves will not be recorded. The average template and/or measurement information can be recorded according to the settings made by the user.

5.3 MANUAL Mode

Under MANUAL mode, users should switch the lead group manually. Users can determine which lead group needs to be recorded and set the recording settings or other parameters according to different lead group.

Operation Method:

- 1) Press MODE/RST key to choose MANUAL mode, which can be discerned by the identifier in the top left corner of LCD screen;
- 2) Press **MENU** key to enter the Menu window to set the record settings. Press it again to return after setup;
- 3) Press **LEAD** left arrow or right arrow key to select leads to be recorded;
- 4) Press **PRINT/STOP** key to begin recording;
- 5) 1mV/COPY key can be pressed to print out 1mV mark while ECG recording;
- 6) Press **PRINT/STOP** key to stop recording after finishing ECG record.

LEAD left and right arrow key can be pressed to switch the lead group during the course of recording. Pressing PRINT/STOP again during the course of recording can stop recording. However, when begin to record later, ID number will change automatically according to the current time. If the ID number needs to be unchanged, the user should adjust it before recording.

5.4 RHYTHM mode

Under Rhythm mode, the user can record 60s rhythm-lead ECG waveform.

- 1) Press **MENU** key to enter the Menu window to set the RHYTHM LEAD or other settings. Press it again to return after setup;
- 2) Press **MODE/RST** key to choose RHYTHM mode;
- 3) Press **PRINT/STOP** key and the alert information "Sampling" will be displayed in the alert information field. When the sampling time reaches 60s, it begins to record;
- 4) It will stop automatically after recording a full rhythm-lead ECG waveform.

Pressing PRINT/STOP again during the course of recording can stop recording.

5.5 USBPRT mode

Under USBPRT mode, ECG report can be printed out through USB printer.

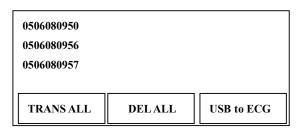
- 1) Connect CARDEXTM 300 to the USB printer;
- 2) Press **MENU** key to enter Menu window to set corresponding options. Press it again to return after setup;
- 3) Press MODE/RST key to choose USBPRT mode;
- 4) Press **PRINT/STOP** key to begin recording. It will stop automatically after recording a full ECG report.

5.6 ECG Recall Operation

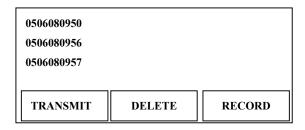
5.6.1 ECG Recall

Press **RECALL** key to enter the recall window where patient files are saved. The recall window allows files to be stored, deleted, printed and transmitted. When there is no space for more files to be stored in the recall window, the message "Mem Full" is displayed on the main interface.

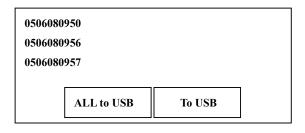
Recall Window (a)



Recall Window (b)



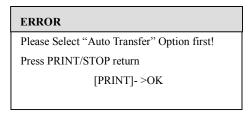
Recall Window (c)



Operation for ECG RECALL:

- 1) Press **RECALL** key to enter the Recall Window (a) where patient files are saved;
- 2) If the user wants to transmit all the files, press Left or Right to choose TRANS ALL, and then press PRINT/STOP or MENU key to transmit all the files; If the "Auto Transfer" option is not selected before transmitting, WARNING (a) will pop up to remind the user to do it first.

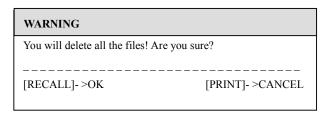
WARNING (a)



Note: Before transmitting patient files, please set the AUTO TRANSFER option in Menu window. Refer to **5.8.5 Transfer Settings** for detail.

3) If the user wants to delete all the files, press Left or Right to choose DEL ALL, and then press PRINT/STOP or MENU key to pop up the WARNING (b). Then press RECALL to delete all the files or PRINT/STOP to cancel deleting;

WARNING (b)



4) If the user wants to import files (The extended-name should be ".dat") from the ECGDATA folder of the U disk to the electrocardiograph, press **Left** or **Right** to choose **USB to ECG**, and then press **PRINT/STOP** or **MENU** key to begin to import;

Note: To import files in U disk to electrocardiograph, there should be some files in the folder named ECGDATA in the U disk. The folder name "ECGDATA" must be capital letters. The user should not change the name of files in the ECGDATA folder.

During the course of **USB to ECG**, if something wrong happens, the electrocardiograph will give the error information. And then the user should do the following:

First, check whether the U disk is connected well, and correct it if necessary.

If the error information is still displayed, the user should check whether some files exist in the ECGDATA folder of the U disk. If nothing is found, the user should build a folder named ECGDATA in the U disk and put some files (The extended-name is ".dat") into the ECGDATA folder.

If the error information is still displayed, then the user should check whether the total number of files in the ECGDATA folder of the U disk and in the recall window of the electrocardiograph has exceeded the limit (The limit of CARDEXTM 300 is 120). If the total number has exceeded the limit, the user should remove some files from the ECGDATA folder of the U disk and then continue to import.

If the error information is still displayed, then the user should check whether there are some files in the U disk having the same name with the files in the electrocardiograph. If it is true, the user should remove these files from the U disk, or delete these files in the electrocardiograph, and then continue to import. (Under this situation, this error information is "The same file found! Press PRINT/STOP return".)

After finishing importing files, the electrocardiograph will give a distinct indication.

Note: Only FAT format should be selected when formatting the U disk.

If the user wants to copy all the files from the electrocardiograph to the U disk, press **Left** or **Right** to choose **ALL to USB**, and then press **PRINT/STOP** or **MENU** key to begin to copy; after a while, all the files will be copied into the ECGDATA folder of the U disk automatically.

During the course of **ALL to USB**, if something wrong happens, the electrocardiograph will give the error information. Then the user should check whether the U disk is connected well, and correct it.

Note: The process of **TRANS ALL**, **USB to ECG** or **ALL to USB** needs a long time to finish, and the user should be patient. During the course of copying, the U disk should not be pulled out.

5) Press **Up** or **Down** to choose one of the files in the recall window;

If the user wants to transmit this file, press **Left** or **Right** to choose **TRANSMIT** button, and then press **PRINT/STOP** or **MENU** key to transmit the file; If the "Auto Transfer" option is not selected before transmitting, WARNING (a) will pop up to remind the user to do it first.

If the user wants to delete this file, Press **Left** or **Right** to choose **DELETE** button, and then press **PRINT/STOP** or **MENU** key to pop up the WARNING (c). Then press **RECALL** to delete this file or **PRINT/STOP** to cancel deleting;

WARNING (c)

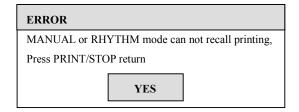
WARNING	
You will delete this file! Are you su	ure?
[RECALL]->OK	[PRINT]->CANCEL

If the user wants to record this file, press **Left** or **Right** to choose **RECORD** button, and then press **PRINT/STOP** or **MENU** key to begin recording; Pressing **PRINT/STOP** again during the course of recording can stop recording.

Note: If the user selects USBPRT mode to print, when PRINT/STOP key or MENU key is pressed, the electrocardiograph begins to analyze data, and after 8 seconds the USB printer begins to print.

Note: MANUAL or RHYTHM mode cannot support recall printing.

If the user selects MANUAL or RHYTHM mode to record, WARNING (d) will pop up. WARNING (d)



If the user wants to copy this file to the U disk, press **Left** or **Right** to choose **To USB**, and then press **PRINT/STOP** or **MENU** key to begin to copy;

6) Press **RECALL** key to return to the main interface.

Note: To save the ECG data to the recall window as patient files, please refer to **5.8.5 Save Option Settings**.

5.6.2 ECG Copy

Under auto mode, once a complete ECG was recorded, pressing 1mV/Copy key can recall the electrocardiogram that was recorded last time.

Pressing PRINT/STOP during the course of recording can stop recording.

Note: After recording is finished, if RECORD FORMAT or SAMPLE MODE is changed, ECG Copy is not permitted.

5.7 Using the Menu System

5.7.1 Entering and Exiting the Menu

Press the MENU key to enter the menu, and press the MENU key again to exit the menu.

AC Filter : On
EMG Filter : Off
DFT Filter : 0.15Hz
Lowpass Filter : 100Hz

5.7.2 Moving in the Sub-menus

Press **Up** or **Down** to choose the setting items;

5.7.3 Parameter Modification

Press Left or Right to modify a parameter;

Note: When modifying Record Mode or Sensitivity on the main interface, to save the modifications, the user should enter the menu interface and exit. After that, the user will see the modifications in the main interface when he turns on the electrocardiograph again.

5.8 Settings

5.8.1 Filter Settings

AC Filter : On
EMG Filter : Off
DFT Filter : 0.15Hz
Lowpass Filter : 100Hz

Four filters can be set in the MENU window. They are: AC FILTER, EMG FILTER, DFT FILTER and LOWPASS FILTER.

AC FILTER

AC FILTER suppresses AC interference without attenuating or distorting the ECG. Select **On** to turn on the function and select **Off** to turn off.

EMG FILTER

EMG FILTER suppresses disturbances caused by strong muscle tremor. The cutoff frequency is user-defined at 25Hz, 35Hz or 45Hz. Select Off to turn off the function.

DFT FILTER

DFT FILTER greatly reduces the baseline fluctuations without affecting the ECG signal. The purpose of this filter is to keep the ECG signals on the baseline of the printout. The setting value is the low limit of the frequency range, including **0.05Hz**, **0.15Hz**, **0.25Hz**, **0.5Hz**, and is normally set to **0.15**Hz.

LOWPASS FILTER

LOWPASS FILTER restricts the bandwidth of input signal. The cutoff frequency is user defined at **150Hz**, **100Hz** or **75Hz**. All the input signals whose frequency is higher than the setting cutoff frequency will be attenuated.

5.8.2 Recording Settings

Recording Format : 3Ch
Recording Grid : Off
Recording Speed : 25mm/s
Recording Length : Short

RECORDING FORMAT

When **RECORDING FORMAT** is **3Ch**, limb leads will be recorded in 2 groups of 3.

When **RECORDING FORMAT** is **3Ch+1R**, limb leads will be recorded in 2 groups of 3, with one rhythm lead at the bottom of recording paper.

When **RECORDING FORMAT** is **1Ch**, all leads will be recorded one by one in a sequence.

When **RECORDING FORMAT** is **1Ch+1R**, all leads will be recorded one by one in a sequence, with one rhythm lead at the bottom of recoding paper.

RECORD GRID

When **RECORD GRID** is **On**, the dashed grids which are 5 mm by 5 mm will be recorded on the paper.

When **RECORD GRID** is **Off**, dashed grids will not be recorded on the paper.

RECORDING SPEED

Under MANUAL/RHYTHM mode, **RECORDING SPEED** can be set as 5, 6.25, 10, 12.5, 25 or 50mm/s.

Under AUTO/OFF/USBPRT mode, **RECORDING SPEED** can be set as 25 or 50mm/s.

RECORDING LENGTH

Short form means that each lead group will be recorded about 2.5 seconds.

Medium form means that each lead group will be recorded about 5 seconds.

Long form means that each lead group will be recorded about 7.5 seconds.

Longest form means that each lead group will be recorded about 10 seconds.

Note: When RECORDING FORMAT is 1Ch, only Short form is supported in RECORDING LENGTH.

5.8.3 Recording Output Settings

Average Template : 2Ch+1R
Measurement : Off
Interpretation : Off
RR Analysis : On

AVERAGE TEMPLT

When AVERAGE TEMPLT is **2Ch+1R**, limb leads will be recorded in 3 groups of 2, with one rhythm lead at the bottom of recoding paper.

When AVERAGE TEMPLT is **3Ch**, limb leads will be recorded in 2 groups of 3.

When AVERAGE TEMPLT is **Off**, there will be no average template when recording.

RR ANALYSIS

When **RR ANALYSIS** is **On**, RR Analysis results, including RR Interval measurement information, RR Histogram and RR Trend Chart, will be recorded after rhythm wave is recorded in RHYTHM mode.

When **RR ANALYSIS** is **Off**, there will be no RR Analysis results after rhythm wave is recorded in RHYTHM mode.

MEASUREMENT

When MEASUREMENT is **On**, the measure information will be recorded when recording in AUTO mode.

When MEASUREMENT is **Off**, there will be no measure information when recording.

Note: To get the content of MEASUREMENT, please refer to **Chapter 5.9 ECG Record**.

Note: The function of Interpretation is not supported in this version.

5.8.4 Other Recording Settings

Lead Sequence : Standard

Sample Mode : All CH Simu.

Rhythm Lead : II Paper Style : Rolled

LEAD SEQUENCE: Standard/Cabrera

Lead Sequence	Lead Sequence Lead group 1		Lead group 3
Standard	І, ІІ, Ш	aVR, aVL, aVF	V
Cabrera	aVL, I, -aVR	II, aVF, III	V

SAMPLE MODE

1CH Sequent.

Lead is sampled one by one in a certain sequence.

3CH Sequent.

Lead group is sampled one by one in a certain sequence.

All CH Simu.

All leads are sampled simultaneously.

RHYTHM LEAD

The rhythm lead can be one of 7 standard leads: I, Π, III, aVR, aVL, aVF and V.

PAPER STYLE

Rolled thermal paper and folded thermal paper can be selected as recording paper.

Note: If the user sets the PAPER STYLE as folded paper, after ECG recording is completed in Auto mode or RHYTHM mode, recording will stop when a black sign is detected, or it will stop with alert information "Paper Err" when no black sign is detected.

5.8.5 Save and Transmitting Settings

Save Option : Off Auto Transfer : Off

Local IP : 192. 168. 001. 021 Remote IP : 192. 168. 001. 245

SAVE OPTION

When SAVE OPTION is **On**, the ECG data will be saved into the recall window automatically while it is being recorded in AUTO recording mode.

When SAVE OPTION is **Off**, the ECG data will not be saved into the recall window while it is being recorded in AUTO recording mode.

Note: When there is no space for more files to be stored in the recall window, the message "Mem Full" is displayed on the main interface.

AUTO TRANSFER

Note: To transfer ECG data to a PC, Smart ECG-Viewer software of Midmark Corporation must be installed in PC machine. Receive ECG Data window in the software should be opened up, transfer type should be selected, and other settings should be finished.

When **AUTO TRANSFER** is **OFF**, the patient files can not be transferred;

When AUTO TRANSFER is UART AUTO, firstly connect the serial port of PC machine and the RS232 socket of 3-channel electrocardiograph with serial cable recommended by the manufacturer. Then open the Receive ECG Data window of Smart ECG-Viewer software in PC, select the transfer type "Serial Trans", set the right PortNum and press Connect button. Under AUTO mode or OFF mode, ECG data can be transferred through UART port automatically after ECG recording is finished.

When **AUTO TRANSFER** is **Net AUTO**, first connect the net interface of PC machine and the net interface of 3-channel electrocardiograph with Ethernet cable recommended by the manufacturer. Second, open the Receive ECG Data window of Smart ECG-Viewer software in PC, select the transfer type "Net Trans" and press **Connect** button. Then set the REMOTE IP and LOCAL IP in Menu window in 3-channel electrocardiograph. Under AUTO mode or OFF mode, ECG data can be transferred through net automatically after ECG recording is finished.

Note: During the course of transferring or saving data, if the power supply is suddenly cut off, File System error may arise in the electrocardiograph. After the error is displayed, the user should format the File System.

REMOTE IP

IP address of the remote computer which receives ECG data from electrocardiograph through net

LOCAL IP

IP address of electrocardiograph

5.8.6 General Settings

Key Beep: OnQRS Beep: OffExtern Inp/Outp: OffRecord Test: Off

KEY BEEP

When KEY BEEP is **On**, a short beep sound will be made when pressing the control key.

When KEY BEEP is **Off**, there is no sound while pressing the key.

ORS BEEP

During the course of ECG recording, if QRS BEEP is **On**, the unit will make a short beep sound when an R wave has been detected. So in normal recording, continuous and regular sound of beep will be heard.

EXTERN INP/OUTP

External input/output signal interface is equipped in CARDEXTM 300, through which CARDEXTM 300 can receive ECG signal from external equipment, or output ECG signal to other external equipment. Set this item as **On** to turn on the function and **Off** to turn off.

RECORD TEST

Press **Left** or **Right** to start recording test when the record paper has been loaded. Then the triangle wave in effective paper width will be recorded. The status of print head can be estimated from this triangle wave. Press **Left** or **Right** again to stop record test.

5.8.7 System Settings

Demo Setting : Off
Language Setting : English
Lead Setting : 7 Leads
Default Setting : Restore

DEMO SETTING: Select **On** to enter the Demo mode.

LANGUAGE SETTING: The user can set the system language.

LEAD SETTING: The user can set the lead number as 7 or 6. When **6 Leads** is selected, the leads include I, II, III, aVR, aVL and aVF.

DEFAULT SETTING: Select **Restore** to resume default setting value.

Note: In the Parameter Options Column, some parameters' options have no underline, which means these parameters have no default settings. And when the user restores default settings, these parameters will not change.

 Date Mode
 : dd-mm-yyyy

 18-01-2008
 11:30

 ID
 : 0801180723

 Password
 : 0 0 0 0 0 0

DATE MODE: Date mode can be set as dd-mm-yyyy, mm-dd-yyyy or yyyy-mm-dd. After setting, the current date format will change according to the DATE MODE you selected.

DATE&TIME SETTING: Set current Date and time. It will be recorded on the recording paper.

ID: Animal ID number

PASSWORD: Password for entering the advanced control interface

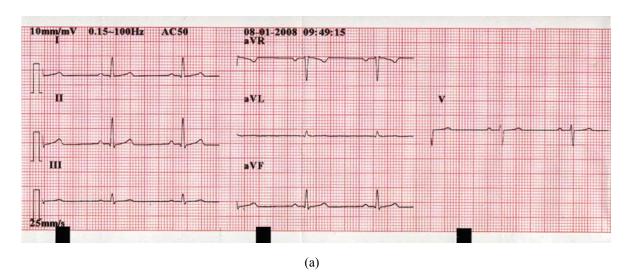
5.8.8 Default Settings

In the following table, the value double-underlined is default setting.

No.	Items	Options
1	AC Filter	On, Off
2	EMG Filter	Off, 25Hz, 35Hz, 45Hz
3	DFT Filter	0.05Hz, <u>0.15Hz</u> , 0.25Hz, 0.5Hz
4	Lowpass Filter	75Hz, <u>100Hz</u> , 150Hz
5	Record Format	<u>3Ch</u> , 3Ch+1R, 1Ch, 1Ch+1R
6	Record Grid	Off, On
7	Record Speed	5mm/s, 6.25mm/s, 10mm/s, 12.5mm/s, <u>25mm/s</u> , 50mm/s
8	Record Length	Short, Medium, Long, Longest
9	Average Template	<u>2Ch+1R</u> , Off, 3Ch
10	Measurement	Off, On
11	Interpretation	Off
12	RR Analysis	On, Off
13	Lead Sequence	Standard, Cabrera
14	Sample Mode	All CH Simu., 3CH Sequent., 1CH Sequent.
15	Rhythm Lead	$I, \underline{II}, III, aVR, aVL, aVF, V$
16	Paper Style	Rolled, Folded
17	Save Option	Off, On
18	Auto Transfer	Off, UART AUTO, Net AUTO
19	Local IP	192. 168. 001. 021
20	Remote IP	192. 168. 001. 245

21	Key Beep	On, Off		
22	QRS Beep	Off, On		
23	Extern Inp/Outp	Off, On		
24	Record Test	Off, Testing		
25	Demo Setting	Off, On		
26	Language Setting	Chinese, English		
27	Lead Setting	7 leads, 6 leads		
28	Default Setting	Restore		
29	Data Mode	dd-mm-yyyy, mm-dd-yyyy, yyyy-mm-dd		
30	Date Setting	24-12-2007		
31	Time Setting	08:23		
32	ID	071224-0823		
33	Password	Password for entering the advanced control interface		

5.9 AUTO mode record



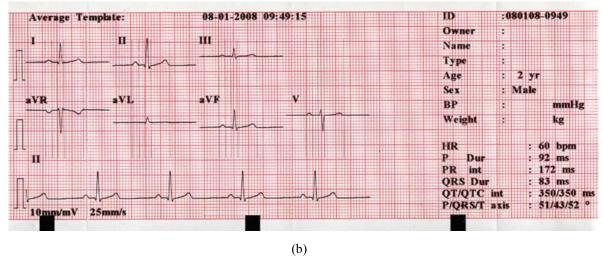


Figure (a) shows the following content:

10mm/mV----Sensitivity

0.15~100Hz----Filter information

AC50----50Hz AC Filter

08-01-2008 09:49:15----Date and time

 Π ----1mV calibration mark

I, II, III, aVR, aVL, aVF, V----Lead name

ECG wave of 7 leads in the format of 3Ch

25mm/s----Paper speed

- Figure (b) shows the AVERAGE TEMPLET (2Ch+1R) and the MEASUREMENT (ON). The items of the MEASUREMENT include:
 - ID, Owner, Name, Type, Age, Sex, BP, Weight, HR (Heart Rate)
 - P Dur----P wave duration: mean of duration of P-wave from several of 12 selected dominant beats:
 - PR int----P-R interval: mean of P-R interval from several of 12 selected dominant beats;
 - QRS Dur----QRS complex duration: mean of duration of QRS complexes from several of 12 selected dominant beats;
 - QT/QTC int----Q-T interval: mean of Q-T interval from several of 12 selected dominant beats/Normalized QT interval;
 - P/QRS/T axis----dominant direction of the average integrated ECG vectors;
- **Note**: Recording under AUTO mode or MANUAL mode, if the Sensitivity is set as 20mm/mV, only one calibration mark will be displayed on the paper.

5.10 RHYTHM mode record

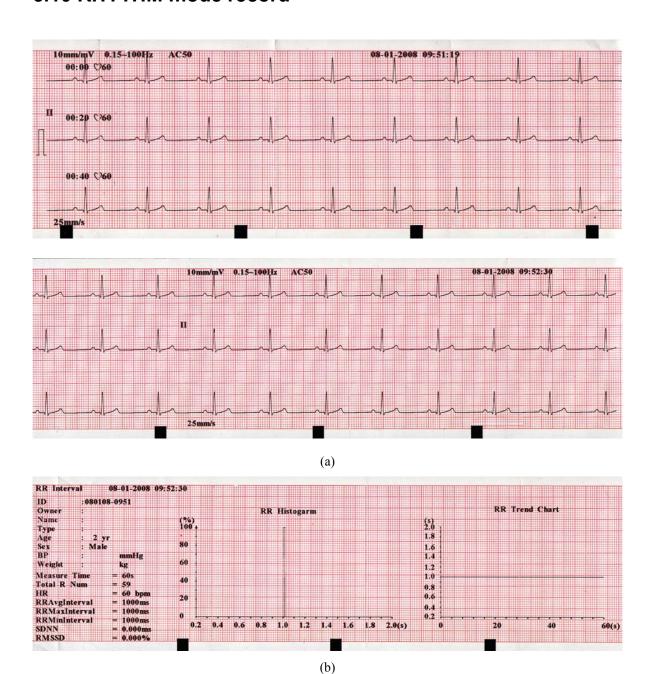


Figure (a) shows the following content:

10mm/mV (Sensitivity)

0.15~100Hz (Filter information)

AC50 (50Hz AC Filter)

08-01-2008 09:51:19----Date and time

 Π (1mV calibration mark)

II (Lead name)

60 seconds rhythm waveform of lead II

00:00, 00:20, 00:40 (Timer)

060 (Heart rate)

25mm/s (Paper speed)

Figure (b) shows RR Analysis Results, including RR Interval measurement information, RR Histogram and RR Trend Chart.

RR Interval measurement information includes the following content:

Current Date & Current Time

Animal Information (ID, Owner, Name, Type, Age, Sex, BP, Weight)

Measure Time

Total R Num (Total R-wave number)

HR (Heart Rate)

RR Avg Interval (Average RR interval)

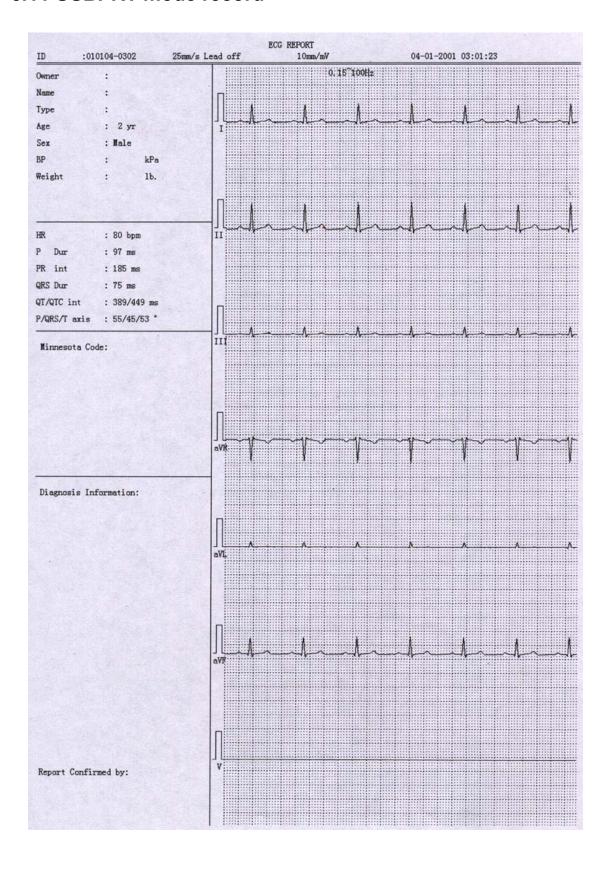
RR Max Interval (Maximum RR interval)

RR Min Interval (Minimum RR interval)

SDNN (Standard Deviation of Normal to Normal Intervals)

RMSSD (The Root Mean Square of Successive Difference)

5.11 USBPRT mode record



As figure above shows, the USBPRT mode record includes:

ID, Record speed, Hint information, Sensitivity, Date and time;

Owner, Name, Type, Age, Sex, BP, Weight;

Heart Rate, P duration, PR interval, QRS duration, QT/QTC interval, P/QRS/T axis;

Minnesota code; (Written by doctor)

Diagnosis information; (Written by doctor)

Report confirmed by; (Written by doctor)

ECG waveform of 7 leads;

5.12 Switch Off

When built-in battery pack used, press **ON/OFF** key directly to turn off the unit after finishing ECG recording.

When mains supply used, press **ON/OFF** key first after finishing ECG recording and then switch off the mains supply by pressing the switch on the left side of the unit. Pull out the plug from the outlet last.

Note: When switching off the device, please operate it according to the sequence above strictly, or else there will be an error on the screen.

6 Alert Information

Alert information will be displayed when there is something wrong. Alert information provided by CARDEXTM 300 and corresponding cause is listed in Table 6-1.

Table 6-1 Hint Information and Causes

Alert Information	Causes
Lead off	Electrodes fall off from the animal or the patient cable falls off from the unit.
BAT WEAK	The built-in battery is weak.
Paper?	Recording paper has not been loaded or it has run out.
PaperErr	Feed paper error.
Sampling/Printing	ECG signal is being sampled / Printed.
Modu Err	There is something wrong with the signal sample module.
Demo	The system is in demonstration mode.
Process	The ECG data is being processed.
Transfer	The patient file is being transferred through UART port or Ethernet.
Mem Full	There is no space for more files to be saved.
Overload	The direct current voltage on an electrode is too high.
Uprinter	A USB printer is connected to the USB interface.
USBExist	A U disk is connected to the USB interface.

7 Technical Specifications

Safety Standards	IEC/EN 60601-1+A1+A2, IEC/EN 60601-1-2+A1, IEC/EN60601-2-25, ANSI/AAMI EC11, IEC/EN 60601-2-51						
	Anti-electric-shock type:			Class I with internal power supply			
	Anti-electric-shock degree:			Ty	Type CF with defibrillation proof		
	Degree of protection against harmful ingress of water:			Sealed equipment without liquid proof			
Classification	Disinfection/st	erilization 1	method:	Re	Refer to the user manual for details		
	Degree of safe presence of fla			-	uipment not suitable for use in presence of flammable gas		
	Working mode	:		Co	ntinuous operation		
	EMC:			Gr	oup I, Class A		
Dimensions	288mm×210mm×70mm						
Weight	About 2.5kg						
Display	192×64 dot single color LCD Screen						
		Transport and Storag		ge	e Working		
	Temperature:	-20°C (-4°F) ~ +55°		C	+5°C (+41°F) ~ +40°C		
Environment	(+)		-131°F)		(+104°F)		
Environment	Relative Humidity:	25%~93%		25%~80%			
	,	Non-Condensing			Non-Condensing		
	Atmospheric Pressure:	700hPa ~1060hPa			860hPa ~1060hPa		
	Mains Supply:		Operating voltage =100V-115V~ / 220V-240V~				
			Operating frequency = 50Hz / 60Hz				
			input power = 35VA				
Power Supply	-		Rated voltage = 14.8V				
			Rated capacity = 2200mAh				
			Charge mode: Constant current/voltage				
			Charge current (standard) = $0.28C_5A$ (600mA)				

		Charge voltage (standard) = (16.8-0.1V)		
		Cycle life ≥ 300 times		
	Power Consumption:	35VA (max)		
Fuse:		T400mA250V Ø5×20 / T200mA 250V Ø5×20		
	Recorder:	Thermal dot-matrix printer		
	Recorder Paper:	Folded thermal paper, 80mm×70mm×200pages Rolled thermal paper, 80mm×20m		
Recording	Effective Width:	72mm		
	Paper Speed:	5mm/s, 6.25mm/s, 10mm/s, 12.5mm/s, 25mm/s, 50mm/s (±3%)		
	Accuracy of data:	±5% (x-axis), ±5%(y-axis)		
	Technique:	Peak-peak detection		
HR Recognition	HR Range:	30 BPM ~300 BPM		
i recog	Accuracy:	±1BPM		
	Leads:	7 standard leads		
	Acquisition Mode:	simultaneous 7 leads		
	A/D Resolution:	12bits		
	Time Constant:	≥3.2s		
	Frequency Response:	0.05Hz ~ 150Hz (-3dB)		
	Sensitivity:	2.5, 5, 10, 20 (mm/mV)		
ECG Unit	Input Impedance:	≥50MΩ(10Hz)		
Locollin	Input Circuit Current:	≤0.05μA		
	Input Voltage Range:	<±5 mVpp		
	Calibration Voltage:	1mV±3%		
	DC Offset Voltage:	±500mV		
	Noise:	\leq 12.5 μ Vp-p		
	Multi-channel Crosstalk	≤0.5mm		
	Filter:	AC Filter: On/Off		

CMRR:			DFT Filter: 0.05/0.15/0.25/0.5	
			EMG Filter: 25Hz/35Hz/45Hz/OFF	
			LOWPASS Filter:150Hz/100Hz/75Hz	
			≥110dB	
	Sampling Frequency:		1000Hz	
Patient Leakage Current:		NC	<10μA (AC) / <10μA (DC)	
		SFC	<50μA (AC) / <50μA (DC)	
Patient Auxiliary Current:		NC	<10μA (AC) / <10μA (DC)	
		SFC	<50μA (AC) / <50μA (DC)	
Dielectric Strength:			4000V rms	
External Input/Output (Optional)	Input:		≥100kΩ; Sensitivity 10mm/V±5%; Single ended	
	Output:		≤100Ω; Sensitivity 1V/mV±5%; Single ended	

8 Cleaning, Care and Maintenance

8.1 Cleaning

CAUTION: Turn off the power before cleaning and disinfection. Mains supply must be switched off if it has been in use.

8.1.1 Clean the Main Unit and Patient Cable

The surface of the main unit and patient cable can be wiped with a clean soft cloth damped in soapy water or non-caustic neutral detergent. After that, remove detergent remainder with a clean dry cloth.

8.1.2 Clean the Electrodes

Remove the remainder gel from the electrodes with a clean soft cloth first. Clean them in warm water and be sure there is no remainder gel. Dry the electrodes with a clean dry cloth or air dry.

8.1.3 Clean the Print Head

A dirty and soiled thermal print head will deteriorate the recording definition. So it should be cleaned at least once a month.

Open the recorder casing and remove the paper. Wipe the print head gently with a clean soft cloth damped in 75% alcohol. For stubborn stain, soak it with a little alcohol first and wipe it off with a clean soft cloth. After air dried, load the recording paper and shut the casing of the recorder.

QCAUTION:

- Prevent the detergent from seeping into the main unit while cleaning. Do not immerse the unit or patient cable into liquid under any circumstances.
- Do not clean the unit and accessories with abrasive fabric and avoid scratching the electrodes.

8.2 Disinfection

To avoid permanent damage to the equipment, disinfection can be performed only when it has been considered as necessary according to your hospital's regulations.

Before disinfection, clean the equipment first. Then wipe the surface of the unit and patient cable with hospital standard disinfectant.

CAUTION : Do not use chloric disinfectant such as chloride and sodium hypochlorite etc.

8.3 Care and Maintenance

8.3.1 Recharge and Replacement of Battery

1) Capacity Identification

Current capacity of the rechargeable battery can be identified according to the battery symbol in the main interface

: Full capacity

: Capacity is limited, and recharge should be taken into account

Battery is weak; and warning message "BAT WEAK" will be displayed on LCD screen. The battery should be recharged immediately

2) Recharge

CARDEX[™] 300 is equipped with recharge control circuit together with built-in rechargeable lithium battery. When connecting with the mains supply, the battery will be recharged automatically. Then the battery recharge indicator light (→□) and the mains supply indicator

light (\sim) will be lit at the same time. During the course of recharging, the symbol " $\stackrel{\blacksquare}{\longrightarrow}$ " will

flash in the main interface. When the capacity of battery is full, the symbol "w" will stop flashing, and the battery recharge indicator light (>) will usually be black. But if CARDEXTM 300 is power off, the light will still be on just because the equipment will not monitor the recharge status; so you need to power on the device to verify the status.

Because of the capacity consumption during storage and transport, the capacity of battery is not full while using at first time. Battery recharge should be considered before first usage.

Note: If the battery has not been used for two or three months, recharging should be done before use the battery again.

3) Replacement

When the useful life of battery is over, or foul smell and leakage has been found, please contact with manufacturer or local distributor for replacement of battery.

⚠WARNING⚠:

- Only the battery of same model and specification provided by manufacturer must be used.
- Danger of explosion -- Do not reverse the anode and cathode when connecting the battery.
- When the battery's useful life is over, contact the manufacturer or local distributor for disposal or dispose the battery according to local regulations.

8.3.2 Recording Paper

Note: Recording paper provided by manufacturer should be used. Other paper may shorten thermal print head's life. And the deteriorated print head may lead to illegible ECG record and block the advance of paper, etc.

Storage requirements:

- ♦ Recording paper should be stored in dry, dark and cool area, avoiding excessive temperature, humidity and sunshine.
- Do not put the paper under fluorescence for long time.
- Be sure that there is no polyvinyl chloride or other chemicals in the storage environment which will lead to color change of the paper.
- ◆ Do not overlap the recorded paper a long time, or else the ECG record may trans-print each other.

8.3.3 Maintenance of Main Unit, Patient Cable & Electrodes

The following safety checks should be performed at least every 24 months by a qualified person who has adequate training, knowledge, and practical experience to perform these tests.

- a) Inspect the equipment and accessories for mechanical and functional damage.
- b) Inspect the safety relevant labels for legibility.
- c) Inspect the fuse to verify compliance with rated current and breaking characteristics.
- d) Verify the device functions properly as described in the instructions for use.
- e) Test the protection ground resistance according to IEC/EN60601-1: Limit 0.1 ohm.
- f) Test the ground leakage current according to IEC/EN60601-1: Limit: NC 500 μA , SFC $1000 \mu A$.

- g) Test the patient leakage current according to IEC/EN60601-1: Limit: NC a.c. 10μA, d.c. 10μA; SFC a.c. 50μA, d.c. 50μA.
- h) Test the patient leakage current under single fault condition with mains voltage on the applied part according to IEC/EN60601-1: Limit: 50μA (CF).

The leakage current should never exceed the limit. The data should be recorded in an equipment log. If the device is not functioning properly or fails any of the above tests, the device must be repaired.

⚠WARNING. Failure on the part of the responsible individual hospital or institution employing the use of this equipment to implement a satisfactory maintenance schedule may cause undue equipment failure and possible health hazards.

1) Main Unit

- Avoid excessive temperature, sunshine, humidity and dirt.
- Put on the dustproof coat after use and prevent from shaking violently when moving it to another place.
- Prevent any liquid from seeping into the equipment, for it will affect the safety and performance of electrocardiograph.

2) Patient Cable

- Integrity of patient cable, including main cable and lead wires, should be checked regularly. Be sure that it is conductible.
- ♦ Do not drag or twist the patient cable with excessive stress while using. Hold the connector plugs instead of the cable when connecting or disconnecting the patient cable.
- Align the patient cable to avoid twisting, knotting or crooking in closed angle while using.
- Store the lead wires in bigger wheel to prevent anyone from stumbling.
- Once damage or aging of the cable patient has been found, replace it with a new one immediately.

3) Electrodes

- Electrodes must be cleansed after use ensuring there is no remainder gel on them.
- ♦ After long-term use, the surface of electrodes will be oxidized because of erosion and other causes. By this time, electrodes should be replaced to achieve high-quality ECG.

CAUTION: The equipment should be sent to a special agency according to local regulation for separate collection after its useful life.

9 Service Warranty

Material and Manufacture

The warranty period for the main unit and the accessories is 24 months from the date of shipment. Midmark Corporation warrants that there's no defect in material and manufacture. During the warranty period, Midmark Corporation will repair or replace the defective part free if the defect has been confirmed as material or manufacture defect.

Software or Firmware

For the software or firmware installed, Midmark Corporation will replace the software or firmware free if the defect has been confirmed during 24 months from the date of shipment. But Midmark Corporation cannot warrant it will not interrupt the use of the product.

Note: All services must be done by the engineers authorized by Midmark Corporation.

Limit of Warranty

The charges for freight is excluded under warranty.

The warranty is void in the case of

- Assembly, extensions, readjustments of any parts;
- Modification and repair by unauthorized persons;
- Subsequent damage caused by improper use or maintenance;
- Replacement or removal of Serial number label and/or manufacturer label;

10 Accessories

⚠ WARNING ⚠: Only patient cable and other accessories supplied by Midmark Corporation can be used, or else the performance and electric shock protection cannot be guaranteed.

Table 10-1 Accessories List

No.	Accessory	Part Number
1	Power cord	01-02-0395
2	Patient Cable, Domestic	CD-0011
3	Flat ECG Clips, Package of 5	CD-0019
4	Paper Roller	CD-0006
5	Thermal Paper	CD-0001
6	Rechargeable Lithium Replacement Battery (2200MAH)	CD-0014
7	Alligator Style Veterinary ECG Banana Clips	CD-0012
8	Carrying Bag	CD-0004
9	PC Viewer Software	CD-0002
10	Ground Cable	015-3091-00

CARDEXTM 300 and accessories are available by contacting Midmark Corporation.



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